House and Senate leaders, in the middle of the night, insisted that the rules be broken to include it.

This process is not fair to the Senate, and certainly not fair to the U.S. military, and certainly—certainly—not fair to the American people. It is time we said no to an abuse of power, no to those who seek to abuse the rules in the name of special interests, and no to turning the Senate into the House of Representatives.

We have rules for a reason. We have rules in the Senate for a reason. Why? To create stability. It creates certainty. These rules serve the majority, and they serve the minority, and they should not be broken because of special interests. They should not be broken because of the powerful.

I am going to vote against cloture today. Now, I know there are some in the majority who have threatened various things if cloture is not invoked. But I say, Mr. President, thankfully, we have Senator STEVENS' own words to tell us what will happen. Here is what the distinguished Senator from Alaska said, the bill manager. He told the Fairbanks Daily News-Miner, this past Sunday:

If a Senate filibuster over ANWR stops the defense bill, the legislation can be quickly modified and passed so there is no impact on the military's finances.

He went on to say:

If we lose, then . . . ANWR will be out.

It is that simple. Senator STEVENS is a man of his word, as he stated on the floor today. And he said if we don't get cloture, the bill goes back to the conferees. Mr. President, I do not know how this vote is going to turn out. We all know it is very close. But I hope ANWR gets taken out. All of us stand with our troops. And all of us want to do what is right for the Senate and for our country. That is why our best course of action is to vote "no" on cloture and follow the roadmap Senator STEVENS himself has provided.

The PRESIDING OFFICER. The majority leader.

Mr. FRIST. America is watching what this body does. And America tells us to win the war on terror. Do not accept retreat and defeat. America is watching this body, and they are telling us to do something about energy prices, that of home heating oil and gasoline prices, and to increase the energy supply in this country.

America tells us to strengthen our porous borders, to enforce the laws of the land. We are a nation of laws. Yes, we are a nation of immigrants, a wonderful nation of immigrants, but a nation of laws.

America tells us to support the victims of Hurricanes Rita and Katrina, and what we are about to vote on in this bill is all of the above. The Democrats should not filibuster our Defense appropriations bill. And that is what we will be voting on in a few minutes.

We are a nation at war. Right now, our troops are engaged on the battlefield with a determined enemy. The consequences of failure to invoke cloture on this Defense appropriations bill, when we have troops in the field, are grave. We have a responsibility not only to fully support our troops when they are at war but a responsibility also to secure our economic viability. We need to reduce that dependence—that dangerous dependence—on foreign sources of oil.

The ANWR provision promises to unlock up to 14 billion barrels of oil, nearly 1 million barrels a day at full production. ANWR has been determined by experts to be the single largest and most promising onshore oil reserve in North America. We need to put these energy resources to work for America to reduce those prices, which every American feels, for our economic security and, indeed, for our national security.

The ANWR provision is responsible. It is reasonable. It is critical to meeting our economic and security priorities

And then we have the victims of Hurricanes Rita and Katrina. They have suffered terrible loss—we have suffered with them—and devastation. This bill, the bill we are about to vote upon, includes a long-term funding stream for gulf coast recovery, as well as the most significant Katrina aid recovery package that Congress has yet allocated, including funds to immediately strengthen and repair the New Orleans levees.

The Defense bill provides \$3 billion for border security to tighten those borders. We are a nation of laws. It is time to enforce them. There is \$1 billion for interoperable communications equipment, the first priority of the 9/11 Commission.

We have long-term funding, as Senator GREGG has spoken to, to help low-income Americans pay their heating bills this winter. I am disturbed—disturbed—that there are Senators who believe it is a victory to kill, to filibuster, to stop, to block this bill.

I urge my colleagues to carefully consider the consequences of the vote they are about to cast and the profound reverberations it will have on America's economic and national security.

A vote for cloture is, indeed, a vote for our troops.

I yield the floor.

CLOTURE MOTION

The PRESIDING OFFICER. Under the previous order, the Chair lays before the Senate the pending cloture motion, which the clerk will state.

The bill clerk read as follows:

CLOTURE MOTION

We the undersigned Senators, in accordance with the provisions of rule XXII of the Standing Rules of the Senate, do hereby move to bring to a close debate on the conference report to accompany H.R. 2863, the Department of Defense Appropriations Act of

Bill Frist, John Cornyn, John Thune, Jeff Sessions, Lindsey Graham, Saxby Chambliss, Richard Shelby, Jon Kyl, Mike Crapo, Mitch McConnell, Ted Stevens, Thad Cochran, C.S. Bond, Conrad Burns, Pete Domenici, Judd Gregg, John Warner.

The PRESIDING OFFICER. By unanimous consent, the mandatory quorum call has been waived.

The question is, Is it the sense of the Senate that debate on the conference report to accompany H.R. 2863, the Department of Defense Appropriations Act of 2006, shall be brought to a close?

The yeas and nays are mandatory under the rule.

The clerk will call the roll.

The legislative clerk called the roll. The yeas and nays resulted—yeas 56, nays 44, as follows:

[Rollcall Vote No. 364 Leg.]

YEAS-56

Akaka	Dole	McConnell
Alexander	Domenici	Murkowski
Allard	Ensign	Nelson (NE)
Allen	Enzi	Roberts
Bennett	Graham	Santorum
Bond	Grassley	Sessions
Brownback	Gregg	Shelby
Bunning	Hagel	Smith
Burns	Hatch	Snowe
Burr	Hutchison	Specter
Chambliss	Inhofe	Stevens
Coburn	Inouye	
Cochran	Isakson	Sununu
Coleman	Kvl	Talent
Collins	Landrieu	Thomas
Cornyn	Lott	Thune
Craig	Lugar	Vitter
Crapo	Martinez	Voinovich
DeMint	McCain	Warner

NAYS-44

The PRESIDING OFFICER. On this vote, the yeas are 56 and the nays are 44. Three-fifths of the Senators duly chosen and sworn not having voted in the affirmative, the motion is rejected.

The majority leader is recognized.

Mr. FRIST. I enter a motion to reconsider the previous vote.

The PRESIDING OFFICER. The motion is entered.

Mr. FRIST. I suggest the absence of a quorum.

The PRESIDING OFFICER (Mr. Burr). The clerk will call the roll.

The legislative clerk proceeded to call the roll.

Mr. FRIST. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER (Mr. THOMAS). Without objection, it is so ordered.

CORRECTING THE ENROLLMENT OF H.R. 2863

Mr. FRIST. Mr. President, I ask unanimous consent that the Senate proceed to the concurrent resolution correcting the enrollment of H.R. 2863

which is at the desk and was introduced by Senator CANTWELL and relates to the conference report to accompany the Defense appropriations bill; I further ask consent that there be 30 minutes for debate equally divided between the two leaders or their designees; that no amendments or motions be in order, and that following that time the Senate proceed to a vote on the adoption of the resolution; I further ask that immediately following that vote the Senate proceed to a vote on the adoption of the conference report to accompany H.R. 2863; provided further that the cloture vote with respect to the Defense authorization be vitiated and the Senate proceed to an immediate vote on adoption of that conference report following the vote on the Defense appropriations measure: I further ask consent that once the House has agreed to the concurrent resolution without amendment, then the Labor-HHS conference report be considered adopted: further that if the concurrent resolution that corrects the enrollment of the Defense bill is not agreed to tomorrow, then passage of the Defense appropriations bill is vitiated.

Finally, I ask consent that if the House has not adopted the resolution, then, notwithstanding the adoption of the adjournment resolution, the Senate would reconvene Thursday, December 22, at 8 p.m.

I further ask consent that following the above action, the Senate proceed to a bill at the desk relating to the extension of the PATRIOT Act, the bill be considered read three times and passed, and the motion to reconsider be laid on the table.

Mr. STEVENS. Mr. President, parliamentary inquiry.

The PRESIDING OFFICER. The Senator will state his inquiry.

Mr. STEVENS. If the Leader's unanimous consent request is granted, the bill is thus sent to the House. Will that bill violate rule XXVIII? I am talking about the conference report. Will that conference report violate rule XXVIII?

The PRESIDING OFFICER. The Senator would have to specify a specific provision.

Mr. STEVENS. I am speaking of the ANWR provisions and Katrina provisions and avian flu provisions. Will they violate rule XXVIII?

The PRESIDING OFFICER. In the opinion of the Chair, those provisions violate rule XXVIII.

Mr. STEVENS. I can't hear the Chair.

The PRESIDING OFFICER. Those provisions do violate rule XXVIII.

Mr. STEVENS. So if this consent is granted, rule XXVIII is violated by this conference report; is that correct? Is that my understanding?

The PRESIDING OFFICER. That issue has not been clearly joined by this agreement.

Mr. STEVENS. How do I join it? I want an agreement that this bill violates rule XXVIII.

The PRESIDING OFFICER. The Senator would need to raise a point of order when the measure is pending.

Mr. STEVENS. I suggest the absence of a quorum. I do suggest the absence of a quorum.

The PRESIDING OFFICER The clerk will call the roll.

The bill clerk proceeded to call the roll.

Mr. FRIST. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER (Mr. CHAMBLISS). Without objection, it is so ordered.

Mr. STEVENS. There has been some confusion. Let me restate my parliamentary inquiry. If sections C and E are removed, would the conference report as thus constituted contain violations of rule XXVIII?

The PRESIDING OFFICER. The Chair is of the opinion that there would be at least one violation of rule XXVIII.

Mr. STEVENS. I can assure you there are many more.

Thank you very much.

Mr. LEVIN. Mr. President, parliamentary inquiry: Has the point of order been be raised against any provision that would be left in this bill?

The PRESIDING OFFICER. No, it hasn't.

Mr. LEVIN. I thank the Chair.

Mr. STEVENS. Wait. I will be glad to make a point of order, if you wish me to do it. Just so I understand the ruling, parliamentary inquiry: Did the Chair just say there is no point of order against this bill?

The PRESIDING OFFICER. The majority leader is recognized.

Mr. STEVENS. I want to make sure I understand this. I would be pleased to make a point of order so the Chair will rule, if you want me to do it. We have an understanding that there are violations of rule XXVIII in this bill.

Mr. REID. Yes, there are.

Mr. STEVENS. Thank you.

Mr. FRIST. Mr. President, I renew my unanimous consent request.

Mr. KENNEDY. Mr. President, reserving the right to object, I had requested in the time that was requested 15 minutes. That is clear. Furthermore, reserving the right to object, I ask unanimous consent to amend the resolution to strike division E, the Public Readiness and Emergency Preparedness Act. This is the provision that provides drug companies with unprecedented immunity from liability which was added to the Defense appropriations bill in the conference during the middle of the night. It does not belong in this bill. I ask unanimous consent.

The PRESIDING OFFICER. Is there objection?

Mr. FRIST. Mr. President, I object. The PRESIDING OFFICER. There is objection.

Is there objection to the unanimous consent request?

Mrs. FEINSTEIN. Mr. President, reserving the right to object, it is my understanding—I ask that it be confirmed—that titles III and VII of the conference report to accompany H.R. 3122 concerning port security and the Combat Meth Act are not in this unanimous consent agreement. Is that correct?

Mr. FRIST. Mr. President, that is correct.

Mrs. FEINSTEIN. Mr. President, let me ask this question. The question is whether I can have such a commitment from the majority leader, since these are both bills that have passed this body unanimously and have also been conferenced by the House, if we could consider them when we come back in January to be the first order of business?

Mr. FRIST. Mr. President, responding to the Senator from California, both of these issues—port security, as well as the methamphetamine—are very important issues that I believe this body unanimously will support. And after consultation with the Democratic leader, we will address those very early when we come back in January or February. They are both very important bills.

Mrs. FEINSTEIN. Does the minority leader concur in that?

Mr. REID. Without reservation.

Mrs. FEINSTEIN. Thank you. January or February. Thank you very much.

The PRESIDING OFFICER. Is there objection to the unanimous consent?

Without objection, it is so ordered.

Mr. FRIST. Mr. President, real quickly, this means that we will have 30 minutes of total debate followed by the concurrent resolution, followed immediately by Defense appropriations, followed by the authorization by voice. That is my understanding.

Mr. LEVIN. Mr. President, reserving the right to object, I don't plan to, and I want to make sure no one needs a rollcall vote—I do not—on the authorization bill. I want to doublecheck with a few people on this side.

Mr. FRIST. We already have unanimous consent, and I believe we will do that.

Mr. LEAHY. Mr. President, might I direct a question to the distinguished majority leader through the Chair?

The PRESIDING OFFICER. The Senator from Vermont.

Mr. LEAHY. Mr. President, if I could have the attention of the majority leader, am I correct in my understanding that the Sununu-Leahy et al 6-month extension of the PATRIOT Act has been included? And that is where we are with the conference report still on the calendar, but the 6 months will be passed?

Mr. FRIST. Mr. President, as part of the unanimous consent is the 6-month extension on the PATRIOT Act.

Mr. LEAHY. Sununu-Leahy et al. Thank you. I thank the Chair. I thank the two distinguished leaders.

If I might note for a moment, both the distinguished Republican leader and the Democratic leader have worked extremely hard on this, as has the Senator from New Hampshire, Mr. Sununu, and Mr. Gregg and others, and, of course, the distinguished chairman of the committee. Senator Specter.

I think this is a reasonable conclusion that will allow the Judiciary Committee to look at some of the questions which have legitimately been raised and would not have been heard had this gone through otherwise.

Mr. REID. Mr. President, I yield 15 minutes to Senator KENNEDY.

The PRESIDING OFFICER. The clerk will report the concurrent resolution

The bill clerk read as follows:

A concurrent resolution (S. Con. Res. 74) correcting the enrollment of H.R. 2863.

The Senate proceeded to consider the concurrent resolution.

The PRESIDING OFFICER. Who yields time?

Mr. REID. Mr. President, I yield 15 minutes to the Senator from Massachusetts.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, will the Chair remind me when I have 3 minutes remaining?

Mr. President, over these last several months in the Senate we have addressed the issue of a potential epidemic, the pandemic flu. There have been two areas of leadership. One has been in our HELP Committee under the chairmanship of Senator ENZI and Senator BURR, where we have tried to work out a whole approach to deal with the area of epidemics and bioterrorist attacks, and another with the leadership of Senator HARKIN, who had asked that we commit some \$8 billion to be able to purchase vaccines and also antiviral drugs for influenza.

I attended the NIH announcement by the President of the United States when he actually requested \$7.1 billion to prepare for a flu pandemic. Those funds were going to be used for public health, first of all, to be able to detect flu outbreaks overseas; secondly, to be able to detect them here at home; then to be able to build containment capacities, what we call "surge" capacity; and, also to have a generously funded vaccine program, and also an antiviral program.

That is really where we were before the Defense appropriations bill.

A number of us on the HELP Committee had a series of negotiations to try to make a bipartisan recommendation to the Senate. We did so on pensions, on higher education, on workforce, and on Head Start. We were able to do so in a number of different areas. And we were moving ahead toward making a recommendation in issues related to the purchase of vaccines and antivirals. There are two important issues to consider with the purchase of pandemic influenza and vaccine antivirals. One is the danger to an individual that is going to take those vaccines or antivirals; and the other is the risk those dangers raise for the companies that produce them. One is the compensation issue, and the other is the liability issue.

We have dealt with these issues on several occasions. We dealt with them with respect to the swine flu. We dealt with these issues with smallpox. We dealt with these issues for childhood vaccines.

One thing we know from experience is, if you do not have an adequate compensation program, no matter how much money you put in for the purchase of vaccines or of antivirals, the program is not going to work. There has to be an assurance that, if first responders and others are going to go out there and take their chance with these new vaccines or other drugs, that if they become grievously ill or sick or even die there will be some compensation for them and for their families for lost wages and medical costs and the like. And there has to be the assurance to the first responders and others that those vaccines are not going to be produced negligently. Otherwise, they will not take the risk of using the vaccines or drugs. That is the framework.

We have to ask ourselves, for the liability and compensation provisions that have been put in the Defense appropriations bill, how do they line up with what has been successful in the past, with bipartisan efforts? These provisions fail in every respect of the word.

First, there is a compensation program that is not funded. It is not funded. It will depend upon future appropriations. If you want to buy a pig in a poke, buy that particular provision. All you have to do is ask my friend from Utah, Senator HATCH, how we have funded the compensation program for the downwinders. Over a long period of time, we did not have the required payments for them, when we know, as a direct result of governmental action, we adversely affected tens, even hundreds, of thousands of downwinders in the State of Utah and in the West more broadly. We have not measured up to our responsibilities to them, and the compensation program before us now is no more adequate. And as a consequence, this compensation program is not going to work.

Not only that, what have we done with regard to the manufacturers? What kind of immunity have we given to them? It's really extraordinarily broad, effectively complete. What they call the "bad actor" provision describes the circumstances in which the immunity from liability fails. And it's really very narrow, because a company's actions have to meet a very narrow definition of willful misconduct.

Page 12 of this 40-page liability section says in order to have any kind of liability, you have to have willful misconduct. This is an act or omission that is taken intentionally to achieve a wrongful purpose; knowingly without legal or factual justification; and in disregard of a known or obvious risk that is so great as to make it highly

probable that the harm will outweigh the benefit.

As if that isn't clear, and narrow, enough, on the same page, underneath this language, is a rule of construction. This rule says that this language establishes a standard for liability more stringent than a standard of negligence in any form or recklessness. So companies are not deterred from acting recklessly, or with gross negligence.

Now that is pretty narrow, but apparently it isn't narrow enough. Right here on page 12, it says that the Secretary of Health and Human Services, in consultation with the Attorney General, must issue regulations that further restrict the scope of actions or omissions that may qualify as willful misconduct.

So "willful misconduct," which should just mean intentional, isn't good enough.

Well, at least we have solved that, right, to make it as narrow as possible? Wrong. Go down to the standard of evidence. The bill changes the standard of evidence in the various trials, to "clear and convincing evidence." That is at the bottom of page 13.

The bill defines a very narrow standard of willful misconduct, and it sets a very high standard of evidence. Shouldn't that be enough? Wrong. You don't have a case against a company under these provisions unless the FDA begins an enforcement case against that company. So if FDA goes ahead and begins the case, you have a chance, right? Wrong again. FDA has to bring it and conclude it successfully before you have any right to proceed with your case.

A person might think, I am not very satisfied with how this liability provision has worked, maybe I will appeal to the courts of this country, right? Wrong. There is absolutely no, no, no, no judicial review when the Secretary of Health and Human Services grants a company immunity by issuing a declaration. No judicial review of that. And there is no judicial review of FDA's decision not to bring an enforcement action. So it is whatever the administration says, whatever the Secretary says, whatever the head of the FDA says, with changed and gimmick rules. This is a sham. There is no possibility of liability here.

Now, we would say, OK, this is bad, but this liability protection is limited to just a few products, right, products that few of us will ever have to use? It actually applies to products—vaccines, drugs, diagnostic tests—for epidemics. We rarely have to worry about epidemics, right? Well, who defines "epidemics"? It is rather interesting who defines epidemics. Senator Domento says diabetes is an epidemic. Senator Frist himself says meth abuse is an epidemic. BILL Frist himself said obesity is an epidemic. Senator Bond says arthritis is an epidemic.

This week in Newsweek Magazine, the Secretary of Health and Human Services, who is going to enforce this provision, says this: We're seeing an epidemic of chronic diseases. Obesity is just one example.

So how many diseases are going to be considered epidemics? A lot, perhaps, but at least we say that is all right, because it is just going to apply to drugs for that particular epidemic disease, right? Wrong again. This provides the same kind of liability protections for any of the drugs or anything else that deals with the side effects of the products for that epidemic disease.

My goodness. Generally around here we measure who the winners are and who the losers are. And we have seen over the last year and a half how the drug companies come out on top, time and time and time and time again. But never, never, never, ever like they have with this sweetheart deal that was stuck into this conference report after the assurances had been given to the conferees that there were no provisions in it with regard to liability.

The Medicare drug law made it illegal for the Government to negotiate prescription drug discounts for seniors. They do it in the VA system, and drug prices for the VA are lower. But we weren't able to permit the government to negotiate drug prices for seniors. The Republican Congress blocked legislation to allow importation of safe and less expensive drugs.

And now we find in this biodefense and pandemic flu provision liability shields for companies that make dangerous drugs, with no compensation for injured patients.

That is a scandal. It has no business being in this bill. The Judiciary Committee requested an opportunity to examine it. It was rejected. We have had no hearings on this particular provision. It is the wrong thing to include in this legislation.

Let me share what one of our colleagues has said about childhood obesity:

The responsibility for this growing epidemic rests with us—the American consumer. We need to get serious about fighting fat.

Let me cite you the language of the provision, the broad definition on page 31 of what gets liability protections under this bill. It says: "Qualified pandemic or epidemic product" means any drug, biological product, any device to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic or limit harm from the pandemic or epidemic or harm from the pandemic or only those products, but any other product, any other product that is produced to deal with the side effects of those products.

This is a scandal. It is a giveaway. It is outrageous. It is rare, if ever, that we give this kind of privileged status to any industry in the country, and give this kind of authority and power solely to one branch of the Government. There is no second guessing. There is no judicial review. There is no further involvement of the Congress. That is basically and fundamentally wrong and we are asking and committing \$3.7 billion to go down this road. It is outrageous and it is wrong.

I am sure that as soon as the Secretary of Health and Human Services issues what is called a declaration for a pandemic or epidemic to give immunity from liability to vaccines or other products, there is going to be a charge to the courts. The constitutionality of this provision is going to go into the Federal district courts and the circuit courts of appeal.

Included in the RECORD is legal authority that I believe shows that this provision, the way it is drafted, is absolutely unconstitutional because of the indefiniteness of the criteria under which the executive branch makes decisions and because there is the real possibility and likelihood of serious injury to individuals without any right to go to court or for judicial review of declarations.

This provision is going to be challenged along the way. We want to tell those in the bio industry—and they are healthy in my State and I have worked with them—if you want to work with us to get an effective compensation program, as we did in the past with smallpox or childhood vaccines, if you want to get an effective provision to deal with liability, one that is responsible and that responsible drug manufacturers will welcome, then we are more than willing to welcome you and to work with you.

But I think we can be certain that this provision will not be effective, and it is misleading the American people to say we are making a downpayment in the development of vaccines for the reasons I have mentioned this evening.

Slipping a provision into a major spending bill late at night at the end of Congressional session is a trick to shield from public debate a provision that is so wrongheaded that it would never stand public scrutiny.

The Republican congressional leadership has snuck yet another special favor to drug companies into the defense appropriations bill.

It is an outrageous provision that has nothing to do with protecting our troops, and it should be dropped from the bill.

This provision allows drug companies to flagrantly disregard basic safety measures in making a broad range of drugs or vaccines, while giving patients who are injured by shoddy products only an empty promise of compensation.

It is cynical to claim that this is what is needed to deal with avian flu.

Drug industry advocates will say that this debate is about trial lawyers, and we have heard phrases like "jackpot justice" and "runaway juries," and tales of endless lawsuits against the firms that make the vaccines. But that couldn't be further from the truth: Senator DODD and I offered a plan that included important legal protections for drug companies that make experimental flu vaccines and other drugs needed to respond to a pandemic or a bioterrorism attack as well as a compensation program modeled after the

Vaccine Injury Compensation Program that already works well for childhood vaccines.

Our proposal follows the successful examples of the past. For swine flu, for the smallpox vaccine and for childhood vaccines, the Government has set up a way to compensate the injured. Whenever Congress has provided an alternative to liability in the past, there has always been an assured means for patients to receive compensation.

The current proposal violates that past practice.

It twists and turns the law to stack the deck against patients, and abrogates basic principles of judicial review. It is no wonder the provision's authors hid it from public debate and didn't let the Senate Judiciary Committee even look at the proposal before it was jammed into the massive conference report.

If they had allowed our Judiciary Committee to examine this proposal, we would have quickly seen its constitutional flaws. I received a detailed analysis of this provision from Professor Erwin Chemerinsky, who is the Alston and Bird Professor of Law and Political Science at the Duke University School of Law.

According to his analysis, the provision gives the Secretary of HHS "unfettered discretion . . . to grant complete immunity from liability" while also "depriving all courts of jurisdiction to review those decisions."

Professor Chemerinsky has found three areas in which the provision infringes the Constitution.

First, the provision delegates powers to the executive branch without the limitation of a prescribed standard. It is an extraordinarily broad delegation—the Secretary decides when to declare emergencies, what diseases or threats to health are covered, which drugs or products will be immunized, which individual citizens lose their right to go to court and recover for injuries caused by the drugs or products, the geographic area in which these rules will apply and the length of time they will apply. This violates the nondelegation doctrine, which says that Congress my not delegate its legislative authority to the executive branch without clear guidelines.

Second, it violates federalism principles by improperly intertwining Federal and State law, making a new Federal cause of action that depends on State law. It also makes the Federal cause of action depend on the FDA or the Attorney General taking an enforcement action. It is a violation of due process, however, to allow official inaction to prevent a person from pursuing his or her rights in court.

Third, the provision completely prohibits judicial review of declarations that provide drug companies with immunity.

The U.S. Supreme Court has repeatedly stressed that the preclusion of all judicial review raises "serious questions" concerning separation of powers

and due process of law. Judicial review of government actions has long regarded as "an important part of our constitutional tradition" and an indispensable feature of that system.

I reserve whatever time I have remaining.

Mr. HATCH. Mr. President, I rise to make a few remarks concerning the Public Health and Emergency Preparedness Act of 2006 which was inserted in a year-end appropriations vehicle, the Department of Defense Appropriations Act.

Protecting the American public against acts of bioterrorism like the 2001 anthrax attacks and natural disease outbreaks such as the risk posed by the avian flu is an important national security priority.

For 4 years, I have worked in a bipartisan manner with my friend from Connecticut, Senator LIEBERMAN, on comprehensive legislation to address this concern.

We have vetted our proposal with literally hundreds of experts over the last 4 years.

We understand full well that our proposal contains a number of bold proposals that challenge our colleagues to make fundamental changes in our biomedical research, public health management, regulatory, antitrust, intellectual property, tax and civil liability systems toward the end of materially increasing our Nation's public/private sector capacity to design, develop and distribute hopefully hundreds of new products to counter the effects for the dozens of known biological, chemical or nuclear threat agents for which we today literally have no diagnostics, vaccines or therapeutic responses.

This is a tall order.

It will likely take 20 or more years to build this capacity to the level we will need to discourage our enemies from attacking us in this manner or, if they do so, to be able to respond in the way that the public will expect to ensure the strength of American society.

We have made some progress in recent years but we have to do much more in this area.

This is the type of issue that takes time, money, creative energy and patience.

We need a Manhattan Project type of effort, and we needed it 4 years ago.

Throughout my years in the Senate, I have worked on dozens of important public health bills.

In my experience, public health bills go better if they are done on a bipartisan basis.

I have also observed over time that, generally speaking, good public health policy turns out to be good politics. I know of no disease or condition that chooses its victims along party lines.

I am pleased that a key concept of the legislation that we introduced in 2002, the "guaranteed market" for those firms that successfully develop certain bioterrorism countermeasures was finally adopted in the Bioshield I legislation passed in the 108th Congress.

In the first session of the current 109th Congress, there has been a great deal of interest in bioterrorism and pandemic diseases. This is good for the American public.

In the Senate, the HELP Committee was infused with new leadership on this issue in the persons of our new chairman, Senator ENZI, and the chairman of the new Bioterrorism and Public Health Preparedness Subcommittee, Senator Burr. Majority Leader Frist and former Chairman Gregg have continued their longstanding involvement on these issues.

Across the aisle, led by a veteran leader in public health issues who has been on the HELP Committee or its predecessors for 43 years, Senator KENNEDY and others including Senators Harkin, Dodd and Clinton have been interested in these issues.

Throughout the Spring of this year the Bioterrorism Subcommittee held a series of bipartisan hearings and discussion roundtables that were attended by leading experts. Throughout the August recess the staffs of the committee members worked on various drafts of bioterrorism legislation that culminated in a markup in September.

Unfortunately, from my perspective, the bill that resulted from the HELP markup did not contain the intellectual property and tax provisions that Senator LIEBERMAN and I have long advocated. Such is the reality of the dance of legislation. But, as has developed in the provisions related to the guaranteed market, liability, and compensation, we believe that the day will come when these ideas from our original legislation are also seen as meritorious.

Subsequent to that markup, the Bush administration unveiled its comprehensive plan to prevent and respond to the potential catastrophic outbreak of human-to-human avian flu transmission.

Throughout the Fall, many Members of Congress, the administration, industry, the public health community and other interested parties worked on various pieces of legislation to respond to these threats. Unfortunately, as sometimes happens at the end of very busy congressional sessions, not everyone was able to work together at the same time.

For a variety of factors, we have now arrived at a point where a potentially integral piece of an effective legislative response to bioterrorism and pandemic threats has been inserted into the Department of Defense appropriations bill. Using year-end appropriations bills as vehicles can be an opportunity to solve important problems but, sometimes, can pose a risk that an inadequately vetted measure becomes law.

As many who are not members of the esteemed Appropriations Committee, I have a preference for the regular order of the authorization process. In all candor, from time to time in my career, I have availed myself of appropriations vehicles to move authorization bills

that I desired to see passed. Sometimes, as shocking as it sounds, there is gambling in Casablanca.

Comes now the newly drafted, and redrafted and redrafted, Public Readiness and Emergency Preparedness Act.

Both Senators FRIST and GREGG must be singled out in the Senate for their efforts to develop and move this new bill. In the House, I understand that Speaker HASTERT and Chairman BAR-TON, even as he was hospitalized, are largely responsible for this effort.

All of these good and earnest members should be recognized for attempting to tackle two of the most vexatious policy and legal issues confronting us in this critical area: liability; and compensation reform.

We need to encourage the private sector to work vigorously on scores of new, potentially dangerous drugs and biological products designed to counter both natural and bioterroist threat agents. That is what liability reform is all about.

At the same time, if some of these products—some of which will never be tested in human clinical trials since it would be unethical to infect a patient with a microbe like the Ebola virus just to see if a potential treatment were safe and effective—turn out to injure and even kill patients, there must be a fair and funded system of compensation.

Some critics are already falsely charging that these new provisions are nothing but a Republican gift to the drug industry during the Christmas season.

Hogwash.

There should be no doubt that the sole intention of the principal drafters of this legislation is to help devise a system that will increase the readiness of our country to respond to bioterrorist or natural public health threats.

I also think it is way past time that Members of this body and others stop unjustifiably vilifying the pharmaceutical industry. Due in large part to the unique partnership between the public and private sector biomedical research enterprise—undergirded by the substantial annual \$28 billion taxpayer investment in the National Institutes of Health—we are on the verge of a revolution in our understanding of human health and disease. Let's just hope that neither the avian flu not the bioterrorists strike before we have developed the means to defeat these threats.

We will not defeat biological enemies with bullets or battleships. It will be accomplished with basic biological knowledge and the applied know-how required to translate ideas from the lab to the patient's bedside.

Integral to this system and to our national security is the too often-maligned pharmaceutical industry.

They are tough, profit seeking companies. They are often their own worst enemies. They are not always right.

But nor are they always wrong. The products they produce are aimed at

preventing and treating diseases and reducing suffering. And that is not the worst business to be in by any means.

The situation is that we are confronting an enormous chicken-and-egg problem in developing new vaccines and countermeasures due to the fact that in the last several decades product liability exposure has drastically reduced our domestic vaccine production capability. I understand that in 1976, 26 companies produced vaccines for the U.S. market. This year, only five companies produce vaccines sold in the U.S. and only three have U.S. production facilities.

This constitutes both a public health and national security challenge that must be addressed.

While I have concerns about many of the precise provisions in this new language, I recognize and commend my colleagues for attempting to solve a problem that needs solving.

I have great respect for the majority leader, especially as he attempts to navigate this year's exceedingly complex package of pending bills which include the budget reconciliation bill—the first such measure in nearly 10 years—the PATRIOT Act, the Labor-HHS appropriations bill, as well as the Department of Defense authorization and appropriations bills. This is a tall order by any standard.

Although I urged the Leader not to include this new bill in the year-end legislation, I told him that I would not vote against this measure if it were part of one of the year end, must pass vehicles.

I did this largely out of deference to our majority leader.

For reasons that I will explain, if it came to a simple up-or-down vote on this measure as currently drafted, I could not yet support it and would vote no.

If this measure does in fact become enacted into law, I will be open to considering further modifications in this language should our study of this new language indicate that changes are advisable.

Many will question whether this bill, in its current form, contains too much indemnification and not enough compensation. This is a fair question.

For example, the funding mechanism in the bill does not appear to be guaranteed.

I have been down the hard road of discretionary funding with respect to the Radiation Exposure Compensation Act, which I authored, and I cannot say that I would recommend such an important program to be subject to the uncertainties of less than stable, certain funding.

Still others will question why the bill provides for no judicial review, apparently even by the United States Supreme Court, for certain actions by the Secretary of Health and Human Services?

There will be concern that the bill does not allow adequate judicial review to assure that the Secretary has not

acted either arbitrarily or capriciously in certain circumstances.

Because of the great significance of this measure, I suggest that Chairmen ENZI and SPECTER hold hearings on this language once the Congress reconvenes after the holidays.

It is, for example, important to learn what the administration thinks about this new bill and whether, upon reflection, it would urge some refinements.

I have not seen a Statement of Administration Policy on this measure.

Nor have I seen a Congressional Budget Office score so it is a little unclear to me how much this new section would cost.

The administration will be called upon to administer a new compensation program and we need to know how they plan to implement this program and whether they have any suggestions to improve the operation of this program.

As well, I would not be surprised if more Members and other interested parties will want to weigh in on the structure of the new compensation program, which is based in large part, on the current smallpox vaccine injury compensation program.

As our experience with the asbestos legislation teaches us, there is always great interest in the level of compensation injured citizens may receive, especially if they give up their possible tort remedies.

I note that there is a higher standard imposed upon the Secretary in constructing an injury table under this new bill than must be met under the current smallpox vaccine injury compensation law. Many will want to know exactly what is intended and what the practical effect of this new standard will be on the health experts who will advise the Secretary in this critical area.

There are also many questions that must be explored with respect to how the liability shield will operate in prac-

Let me state clearly that I favor a strong liability shield so that many pharmaceutical and biotechnology firms will enter this critically important field of research and development. The fact is today that there exists a pervasive climate of apprehension about product liability and litigation exposure and this is chilling the necessary private sector activity.

Clearly something must be done. It is not so clear that the new liability language is yet as good as it needs to be. For example, the way in which the willful misconduct and FDA defense provisions operate together in the context to potential court challenges merit particular attention. As well, the policy and business-behavioral ramifications of drawing a hard line between all forms of negligence and wilful misconduct deserve careful thought and analysis.

In the case of dual use products, such as antibiotics, it appears that, should a bad batch of drugs be made due to ordi-

nary negligence, a patient injured when taking the product for a normal, garden-variety infection will have a much greater range of legal remedies than a person who took a pill from the same adulterated production batch but under a Secretarial declaration of a public health remedy. It is not readily apparent why this should be the case.

There may be ways to further improve and refine these provisions and other parts of the bill as well. For example, consideration is warranted with respect to whether there ought to be a subrogration provision in certain cases when the Federal Government must compensate patients for injuries caused by negligent or grossly-negligent actions of manufacturers, distributors, or others connected with developing the drug or delivering it to patients.

In any event, I think we should keep an open mind to viewing this new language as something as a work in progress.

Rather than embarking down a path of political who-struck-John on how this new section got into the bill and who drafted this provision or that provision, I think the public will be better served if we focus our future efforts on evaluating what the bill does and deciding whether there are ways we can make it better.

One thing is certain. If we do not find a better way to unleash the creative efforts of the private sector in researching and developing a panoply of new products designed to diagnose, prevent and treat bioterrorist and natural threats, the health and welfare of our Nation cannot be secure

We have a big job ahead of us.

I urge that we move forward in a constructive, bipartisan effort to further improve the Public Readiness and Emergency Preparedness Act that has been placed in the DOD appropriations bill conference report. If others are willing to proceed in this fashion, I am certain that Senator LIEBERMAN and I, and many others, stand ready to discuss and refine this and any other piece of related legislation.

The PRESIDING OFFICER (Mr. VOINOVICH). Who yields time?

The Senator From Alaska.

Mr. STEVENS. Mr. President, I want to make sure everyone understands what we have done. I worked 3 months of my life on this bill, primarily to find a way to help the people whom I saw in New Orleans. But this unanimous consent agreement strips sections C and D out of the bill. That section D allocated the funds that were to be received from the development of ANWR and the spectrum money that we expect to come into the Treasury in excess of what was estimated in the budget and earmarked it to a gulf recovery fund and earmarked it to the LIHEAP program under a different formula than the existing formula.

The net result is that those who are going to vote for the separate resolution—and I shall vote against it—will

be taking money from the first responders. Let me go through that. There was \$3.1 billion for our first responders, for homeland security needs. We had \$1 billion for our farmers and ranchers for farm conservation programs. The gulf coast recovery fund was estimated to have \$5 billion in bonus bids and \$40 billion in royalties over the total production years of ANWR. It would have committed 50 percent to Louisiana, 25 percent to Mississippi, 10 percent to Alabama, 10 percent to Texas, and 5 percent to Florida.

When we remove that, we do remove the \$2 billion emergency spending for LIHEAP, and we remove the \$3.1 billion for border security. That is money that was there. It was not funny money. It was money for this year.

So when you go back to New York, will you tell them why? That first responder money was \$1,750,000,000 for the cities of New York, Los Angeles, San Francisco, Miami, Boston, Washington, C, Chicago, Philadelphia, and Houston. I showed before the list of all the people who supported that.

In terms of the preparedness grants for avian flu response, and for evacuation routes, refugee feeding and housing in the event of another disaster: \$1 billion. But above all, the \$1.1 billion in 2006 money for border security for the Northern border and the Southern border, we were overwhelmed with support for that. By voting for this, you will take it out. You are taking out C and D. You are taking out all the funding.

Now, what does that mean? It means that next year when we get the budget they will pick up the estimates we were able to make. The money for ANWR will next year be, I believe, estimated-I am sure it will; I have a letter—at \$10 billion. This year it was \$5 billion. That \$5 billion that was in the budget will not be available to Louisiana. It will not be available to the disaster area. The \$10 billion we estimated in addition to the \$10 billion that is already in the budget for spectrum auctions will take place in 2008 and 2009. Actually, the FCC believes it is going to be \$28 billion. We had used \$8 billion in addition to the \$10 billion that is in the budget. That, next year, will also be estimated, and it will be used by the budget. So that money is not going to be available for these things that Senator Cantwell's resolution will deny.

Senator Cantwell has authored this resolution to take out of the bill all of this money that we worked so hard to find a way to justify. We took future revenues coming into the Treasury, held them in the Treasury and earmarked them for specific purposes when they would arrive. We were told to have every reason to expect that money would come in. And the House agreed with us and allowed two separate emergency things to take place. One was \$1.1 billion for border security. The other was \$2 billion for LIHEAP for those who are in States that are af-

fected by the current formula. That is primarily the Midwestern States and Maine.

But I want the Senate to know the work we did in finding this money and finding a way to hold it in the Treasury, it will not be held any more. This amendment takes out of the bill sections C and D. That means next year you will not find money on this approach for the help for the disaster areas or to deal with LIHEAP or to deal with homeland security. And \$3 billion was earmarked in that fund when the money came in. It was to go to homeland security. We earmarked it. No future budget could use it.

By taking C and D out, by voting for it—all of you—I am going to go to every one of your States, and I am going to tell them what you have done. You have taken away from homeland security the one source of revenue that was new revenue. It was money that should have been used for disaster. It should have been used for homeland security. And I am sure that the Senator from Washington will enjoy my visits to Washington because I am going to visit there often.

This was wrong. We should have kept sections C and D in this bill. This was something that we studied. We went with CBO. We talked to everyone possible. Everyone understood it in the House, what we did. The Senate refused to even look at it. I think most of you voted for it without even looking at it. California has lost its money for disasters in the future from that revenue source. It will have to find some way through the budget to compete with everybody else next year in a declining budget year. Because as the interest on the national debt goes up, there is less money to allocate for existing programs. I predict next year will be the toughest budget year in history.

But we took money from 2008, 2009, 2010, and we earmarked it. One thing you did not notice, we put in borrowing authority. In the event there is a disaster, the Secretary could go to Treasury and say: Mr. Secretary of Treasury, I exercise the borrowing authority and get that money right now. Did you know that? I bet half of you—none of you—read the bill, none of you read the bill. But I am going to explain the bill to everyone in the country—the homeland security bill, the first responders, the interoperability part of it, the part of equipment for first responders.

The total amount of this bill has been destroyed by the Cantwell amendment. And I want to make sure everyone understands it. Emergency assistance for seniors and low-income Americans: That \$2 billion was at a different theory, different formula than the existing law. We made it available to those in great need this winter. By this amendment, by voting for it, you take it away. Go ahead and vote for it. I am going to vote against it because I know what I did. I found and spent a lot of time with those who handle budget matters and particularly the CBO. Ask

them. I will show you the letters. They said I was right, that was new revenue coming into the Federal Government. Everyone expects it, and we earmarked it for those things that we all believe in now.

Next year, are you going to give it to homeland security? Are you going to give it to border security? Are you going to give them \$2 billion for LIHEAP? By the way, it did not have to be spent this year. It could carry over. It is to be used when needed, by higher prices. OK? It was not something that was total spending this year.

I do think the hurricane areas are the ones that lost most. There is a \$14 billion estimate in C and D for the hurricane area: \$7 billion for Louisiana, \$3.5 billion for Mississippi, \$1.4 billion for Texas, \$1.4 billion for Alabama, and \$1.2 billion for Florida.

Mr. President, this Senator has tried to do what is right. In the last month or 2 months, I have been pilloried by almost every newspaper in this country because of what has been said on this floor and what has been said by Members on the other side of this body. I have been called a liar. I have been told that I violated the rules. I have been told I did things in the middle of the night when no one knew it. I have been told almost everything. Even my grandchildren asked my son: Is that right?

I ask the Senate: Is that right? Should I lose the reputation I have gotten for 37 years in the Senate? No one has ever questioned my integrity before this year. Well, we had one little thing—I see an action from the Chair—about an ethics matter in my State, but that, too, was misunderstood. And I am glad to see that—I hope that has been put to rest. But in any event, no one has really questioned my actions here on the floor.

But they have been. People I have known on the other side, on a first-name basis, have come to me and talked to me about their problems—each one of you. Many of you have spoken here and said things that are not true, and you know they are not true. As I said, one Senator said something so bad, I asked for an apology. I would not accept his apology now.

Mr. President, I am going to go home, and I am going to think about this, and I am going to try to figure out what to do next year. But I know one thing, the 3 months I spent on this to try and help the people in the disaster area, with the sincere belief in the-how many of you have been to the disaster area? Did you spend a couple of days down there, as I did? Did you go and look at it? Did you see the miles and miles of homes that are gone? Did you see a great big barge, bigger than this room, on top of a schoolhouse? Did you see miles and miles of levees just laid down? Did you see the devastation as that tsunami came up that channel that man dug from New Orleans to the Did you see that? Did you see how it devastated the land, and all the plant life is now dying because it was inundated in saltwater?

The earthquake in my State did that. I saw one town disappear. I saw a third of my city, Anchorage, disappear. You have to have had that experience to understand how I felt when I went to New Orleans.

You people didn't believe it. Many of you said I did this for political reasons, just a crass thing, pick up some money and give it away for votes. I never asked one of you for a vote. I talked to some of you about how you should vote, but I never went to you and said: You have to vote for me. You wouldn't be voting for me; it was voting for the people who would have been helped.

This has been the saddest day of my life. It is a day I don't want to remember, and I am sorry to see it come to an end. Because I am drawing the line now with a lot of people I have worked with before. I really am. I can't put in my mind the amount of time, the days I have spent with you working on your problems, and to know you said about me the things you said in the last 2 months. I say goodbye to the Senate tonight. Thank you very much.

The PRESIDING OFFICER. Why vields time?

Mr. REID. I yield back the time on this side.

Mr. FRIST. I yield back the time on our side.

The PRESIDING OFFICER. The question is on agreeing to the concurrent resolution, S. Con. Res. 74.

Mr. REID. I ask for the yeas and nays.

The PRESIDING OFFICER. Is there a sufficient second?

There is a sufficient second.

The clerk will call the roll.

The bill clerk called the roll.

Mr. McCONNELL. The following Senators were necessarily absent: the Senator from South Carolina (Mr. DeMint), the Senator from New Hampshire (Mr. Gregg), the Senator from Arizona (Mr. McCain), and the Senator from Rhode Island (Mr. Chaffee).

Further, if present and voting, the Senator from South Carolina (Mr. DEMINT) would have voted "nay."

Mr. DURBIN. I announce that the Senator from New Jersey (Mr. CORZINE), the Senator from Connecticut (Mr. DODD), and the Senator from Indiana (Mr. HARKIN) are necessarily absent.

The PRESIDING OFFICER (Mr. Burr). Are there any other Senators in the Chamber desiring to vote?

The result was announced—yeas 48, nays 45, as follows:

[Rollcall Vote No. 365 Leg.]

YEAS-48

Akaka	Dayton	Leahy
Baucus	DeWine	Levin
Bayh	Dorgan	Lieberman
Biden	Durbin	Lincoln
Bingaman	Feingold	Lugar
Boxer	Feinstein	Mikulski
Byrd	Inouye	Murray
Cantwell	Jeffords	Nelson (FL)
Carper	Johnson	Nelson (NE)
Clinton	Kennedy	Obama
Coleman	Kerry	Pryor
Collins	Kohl	Reed
Conrad	Lautenberg	Reid

Rockefeller Schumer Specter Salazar Smith Stabenow Sarbanes Snowe Wyden

NAYS-45

	NA 1 5—40	,
Alexander	Dole	Martinez
Allard	Domenici	McConnell
Allen	Ensign	Murkowski
Bennett	Enzi	Roberts
Bond	Frist	Santorum
Brownback	Graham	Sessions
Bunning	Grassley	Shelby
Burns	Hagel	Stevens
Burr	Hatch	Sununu
Chambliss	Hutchison	Talent
Coburn	Inhofe	Thomas
Cochran	Isakson	Thune
Cornyn	Kyl	Vitter
Craig	Landrieu	Voinovich
Crapo	Lott	Warner

NOT VOTING—7

Chafee Dodd McCain Corzine Gregg DeMint Harkin

The concurrent resolution (S. Con. Res. 74) was agreed to, as follows:

S. CON. RES. 74

Resolved in the Senate (the House of Representatives Concurring), That, in the enrollment of the bill (H.R. 2863) making appropriations for the Department of Defense for the fiscal year ending September 30, 2006, and for other purposes, the Clerk of the House of Representatives shall make the following corrections:

Strike Division C, the American Energy Independence and Security Act of 2005 and Division D, the Distribution of Revenues and Disaster Assistance.

Mrs. BOXER. I move to reconsider the vote.

Mrs. FEINSTEIN. I move to lay that motion on the table.

The motion to lay on the table was agreed to.

NOTICE

Incomplete record of Senate proceedings.

Today's Senate proceedings will be continued in the next issue of the Record.